

10/589562

IAP11 Rec'd PCT/PTO 16 AUG 2006

PATENT  
32860-001072/US

**IN THE U.S. PATENT AND TRADEMARK OFFICE**

Applicant(s): Klaus ABRAHAM-FUCHS et al.  
Int'l Application No.: PCT/EP2005/050401  
Application No.: NEW  
Filed: August 16, 2006  
For: METHOD FOR VERIFYING THE FEASIBILITY OF A  
MEDICAL STUDY USING ACCEPTANCE CRITERIA FOR  
PATIENTS

---

**INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION CONCURRENT WITH THE  
FILING OF A NEW PATENT APPLICATION)**

Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314  
**Mail Stop PCT**

August 16, 2006

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

**I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION**

The patents, publications, or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

**II. COPIES**

- ☐ Submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- ☒ This application is a National Phase of a PCT application. Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should be forwarded from the International Search Authority. If copies are needed, please contact the undersigned.

- ☒ Because the present application is being filed after June 30, 2003, no copies of the U.S. patents or U.S. patent application publications which are listed on the attached Form 1449 are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any foreign patent documents or non-patent literature listed on the attached Form 1449 are enclosed herewith.

**III. CONCISE EXPLANATION OF THE RELEVANCE**  
(check at least one box)

- a. ☐ **DOCUMENTS IN THE ENGLISH LANGUAGE**

Some of the attached patents, publications, or other information in the English language do not require a statement of relevancy.

- b. ☒ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

Many of the documents have been discussed in the PCT Search Report, the PCT Preliminary Examination Report, and/or throughout the specification. The PCT Search Report and PCT Preliminary Examination Report, along with a German translation aid translating key terms into English, indicate the degree of relevance found by the PCT Office, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

- c. ☒ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

- d. ☐ **OTHER**

The following additional information is provided for the Examiner's consideration.

Applicant encloses a copy of the German Office Action issued on December 14, 2005 in the corresponding German priority application, namely DE 10 2004 052 547.1.

- e. ☐ **EQUIVALENCY DOCUMENTS**

10/589562

IAP11 Rec'd PCT/PTO 16 AUG 2006

e. ☐ EQUIVALENCY DOCUMENTS

FEES

This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 08-0750.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

By:   
Donald J. Daley, Reg. (No. 34,313)

DJD:dpg

P.O. Box 8910  
Reston, Virginia 20195  
(703) 668-8000

Enclosures:

- ☒ Form PTO-1449(s)
- ☒ Documents
- ☒ International Search Report (PCT/ISA/210 and PCT/ISA/220)
- ☒ International Preliminary Examination Report (PCT/IPEA/416 and PCT/IPEA/409)
- ☐ Fee
- ☐ Other: German Translation Aid

IAP11 Rec'd PCT/PTO 16 AUG 2006

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

Sheet 1 of 2

**Complete if Known**

Application Number

NEW

Filing Date

8-16-206

**First Named Inventor**

# Klaus Abraham-Fuchs

Art Unit

Out range

**Examiner Name**

Lebenslauf

Attorney Docket Number

32860-021072/4's

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

***If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.***

IDNR: 4285 / 02.02.2006

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	NEW
		Filing Date	8-16-06
		First Named Inventor	Klaus Abraham-Fuchs
		Group Art Unit	Unk
		Examiner Name	Unk
		Attorney Docket Number	32860-001022/US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	4	N.H.G. Holford et al.: « Simulation of Clinical Trials », Annual Review of Pharmacology and Toxicology, Vol.40, 2000, pp. 209 – 234, XP002340187	
	5	Pharsight: "Trial-Simulator", Produktprospekt, Mountainview, USA, 2002	

Examiner Signature	Date Considered
-----------------------	--------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.